

Patent
10/785,394

REMARKS

Claims 1-32 are pending in the application. Claims 1, 3-6, 10, 11, 14, 16, 18-21, 225, 26, 29 and 31 have been amended herein (independent Claim 31 has been amended only to correct a typographical error). Claims 1, 16 and 31 are the only independent claims.

First, Applicants acknowledge with thanks the indication that Claims 31 and 32 are allowable over the art of record.

Claims 6-8 and 10 were rejected under 35 USC 112, second paragraph, as indefinite. The issue raised in the Action has been addressed in the foregoing amendments in the manner kindly suggested by the Examiner, to change "inlet" to "supply". Similar corrections have also been made throughout the claims. Reconsideration and withdrawal of the Section 112 rejection are respectfully requested.

Claims 1-6, 8-13, 16-21 and 23-28 were rejected under 35 USC 102(b) as anticipated by US Patent 6,231,594 (Dae et al.); Claims 7 and 22 were rejected under 35 USC 103(a) as being unpatentable over Dae in view of US Patent 5,609,591 (Daikuzono) and Claims 14, 15 and 29-30 were rejected as being unpatentable over Dae in view of US Patent 6,287,326 (Pecor). In view of the foregoing claim amendments and the following discussion, each of the rejections is respectfully traversed and reconsideration is requested.

Independent Claim 1 is directed to a catheter system to change the temperature of blood by heat transfer to or from a circulating working fluid, including a supply lumen to introduce a circulating working fluid to a heat transfer element, wherein the supply lumen is substantially straight through the heat transfer element, and a helical return lumen, helically encircling the substantially straight supply lumen, to extract a circulating working fluid from the heat transfer element. The return lumen has a cross-sectional area greater than the cross-sectional area of the supply lumen to enhance flexibility of the heat transfer element, and the helical return lumen encircles the supply lumen such that blood flows between the helical return lumen and the supply lumen, and turbulence is induced in a substantial portion of a free stream of blood by contact with both the helical return lumen and the supply lumen.

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Independent Claim 16 is directed to a method of providing flexibility in a catheter for use in a system to change the temperature of blood by heat transfer to or from a circulating working fluid, including providing a catheter having a supply lumen to introduce a circulating working fluid to a heat transfer element, wherein the supply lumen is substantially straight through the heat transfer element, and a helical return lumen, helically encircling the substantially straight supply lumen, to extract a circulating working fluid from the heat transfer element, the return lumen having a cross-sectional area greater than the cross-sectional area of the supply lumen to enhance flexibility of the heat transfer element, and circulating fluid through the supply lumen and return lumen to change the temperature of the heat transfer element to a temperature different from a patient temperature, to heat or cool the patient. The helical return lumen encircles the supply lumen such that blood flows between the helical return lumen and the supply lumen and turbulence is induced in a substantial portion of a free stream of blood by contact with both the helical return lumen and the supply lumen.

Each of independent Claims 1 and 16, as amended herein, now recites that the helical return lumen helically encircles the straight supply lumen, and that the helical return lumen encircles the supply lumen such that *blood flows between the helical return lumen and the supply lumen*, and wherein turbulence is induced in a substantial portion of a free stream of blood by *contact with both the helical return lumen and the supply lumen*.

Dac fails to teach or suggest a system to change the temperature of blood by heat transfer to or from a circulating working fluid -- in which blood flows between a helical return lumen and a supply lumen, wherein blood flows between, and contacts, *both* the helical return lumen and the supply lumen, such that turbulence is induced in the free stream of blood because of such contact.

In Dac's catheter, "three outer lumens 108, 110 and 112, are wound around an inner lumen 114", and all "four lumens are thin walled balloons and each outer lumen shares a common thin wall segment (116, 118, 120) with the inner lumen 114" (col. 24, lines 45-51). At "some point along the proximal portion of the shaft, each outer lumen is located over a portion of the shaft having a window (154, 152, 148) to the outflow lumen and the outer balloon lumens have a plurality of slits (158, 156, 150) that are aligned with the windows...[t]he heat transfer

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fluid passes through the slits (158, 156, 150) through the windows (154, 152, 148) and into the outflow lumen 132" (col. 26, lines 34-42). Applicant submits that blood would *not* flow between the "outer lumens 108, 110 and 112" and the "inner lumen 114" of Dac's device and induce turbulence in a free stream of blood based on such flow.

For at least the foregoing reason, each of independent Claims 1 and 16, as amended herein, is believed patentable over Dac and the remaining the art of record.

Dependent Claims 2-15 and 17-30 are believed to be clearly patentable for all of the reasons indicated above with respect to Claims 1 and 16, one or the other from which they depend, and even further distinguish over the cited references by reciting additional limitations.

It is respectfully submitted that all pending claims are now in condition for allowance and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues may be resolved.

Respectfully submitted,

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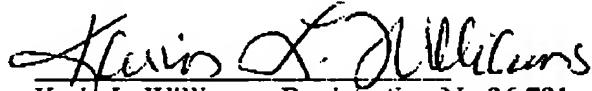
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